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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Arthur E. Uber III

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EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,210	Applicant(s) UBER ET AL.	
	Examiner Manuel A. Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 31,32 and 41-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30,33-40 and 50-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/18/2008, 10/19/2006, and 09/27/2005</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

Claims 31-32 and 41-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 13, 2008.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

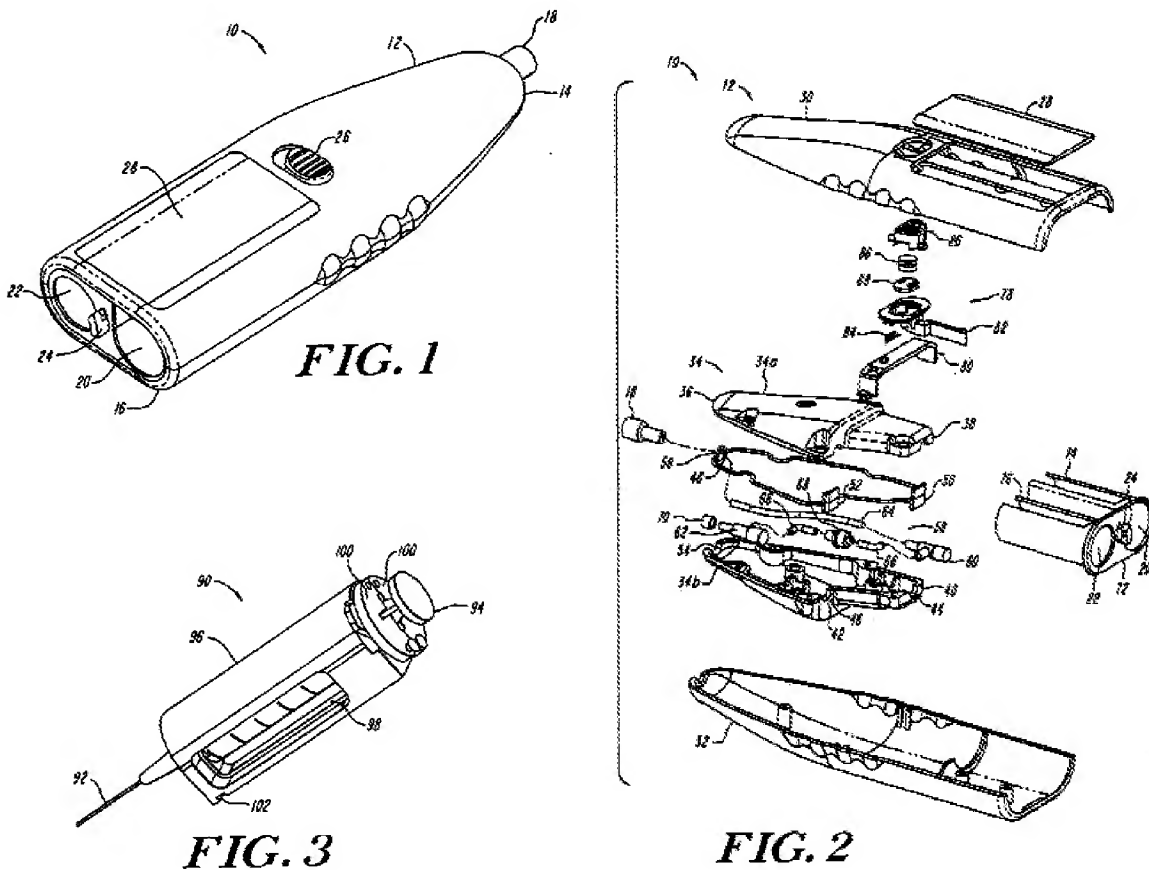
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by **Winkler (US 6,238,374)**.



The Winkler patent shows in figures 1-3, a system for injecting a patient, comprising:

- a container enclosing a hazardous pharmaceutical (syringe reservoir);
- a first pump to deliver a hazardous pharmaceutical to a patient (syringe and syringe plunger (94));

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- a fluid path operably connected to the first pump, the container, and the patient (needle (92)); and
- a hazardous material containment (figures 1 and 3) suitable to confine the hazardous pharmaceutical during connection of the hazardous pharmaceutical container to the fluid path.

Claim Rejections - 35 USC § 103

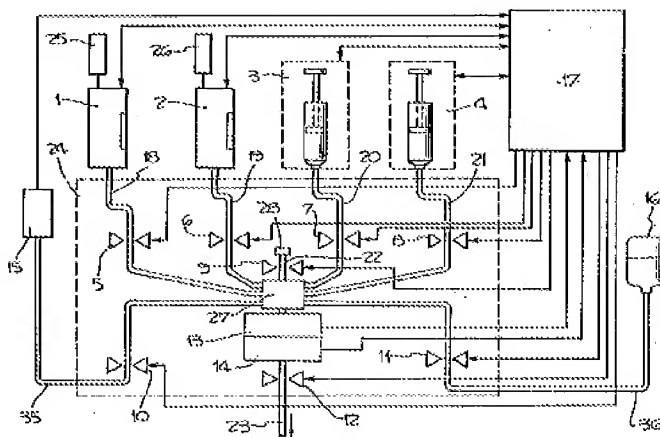
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-12, 14-19, 21, 22, 23, 24, 25, 26, 27 and 28 are rejected under 35

U.S.C. 103(a) as being unpatentable over Polaschegg (US 4,966,579) in view of

Winkler (6,238,374), and in further view of Altman et al. (US 6,547,787; hereafter Altman).



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The Polaschegg patent shows in the figure above, a system for injecting a patient having a container, a pump, and a fluid path operably connected to the first pump, the container, and a patient. Despite showing container means (2,4) in the figure above, Polaschegg is silent about a hazardous material containment suitable to confine a hazardous material. However, redesigning containers (2,4) with hazardous material containment capabilities would have been considered conventional in the art at the time the invention was made as evidenced by the teachings of Winkler.

As discussed in the Section 102 rejection above, the Winkler patent discloses an infuser for transferring hazardous treatment fluids to and from a medical application while protecting both patients and healthcare providers from potentially dangerous spills and leaks. The specification of this patent discloses starting in column 1, line 64, that:

“[t]he infuser includes a spill containing housing having a medical application connecting element and a syringe seat. The syringe seat of the infuser leads to a syringe connecting element that provides a fluid coupling between the syringe and a fluid passage leading to the medical application connecting element. The interior of the housing can be sealed against leaks, for example, by providing the housing in two portions with a gasket provided between the portions. A fluid tight coupling can be formed between the syringe and the interior of the housing by integrally forming a septum with the gasket, and coupling the syringe with the syringe connecting element through the septum. The infuser can thus transfer hazardous fluids from one or more syringes to a medical application with little or no risk of leaks or spills.

The infuser of the invention can also be provided with **two syringe seats** so that two different fluids can be transferred. This configuration is particularly useful where the hazardous fluid must be **diluted or flushed**. In one embodiment, a second syringe connecting element is provided in fluid-tight communication with a second fluid passage. The second fluid passage may connect to the first fluid passage in proximity to the first syringe connecting element, allowing fluid from the second syringe to flush out both fluid passages”.

Based on the teachings of Polaschegg and Winkler, it appears that designing infusion systems having multiple compartments and reservoirs containing different types of fluids would have been considered well known in the art. Importantly, both patents are silent about the infusion of contrast media into the body. However, such intended use would have also been considered conventional in view of the teachings of Altman. The Altman patent demonstrates the conventionality of infusing contrast media into the body using a multi-lumen catheter (column 20, lines 17-34).

Based on the teachings of Winkler and Altman, for a person of ordinary skill in the art, modifying the container and pump means (1,2,3,4) disclosed by Polaschegg with hazardous material containment means, as taught by Winkler, and furthermore, with contrast media infusion capabilities, as taught by Altman, would have been considered “**obvious to try**” since these enhancements were readily available technologies at the time the invention was made, and therefore, would have allowed the artisan to choose from a finite number of predictable solutions, as described by the teachings of the above cited patents, with a reasonable expectation of success.

Claims [13, 20, 29 and 30], [33-40], and [50-79] are rejected under 35 U.S.C. 103(a) as being unpatentable over **Polaschegg** (US 4,966,579) in view of **Winkler** (6,238,374), and **Altman** et al. (US 6,547,787; hereafter Altman) as discussed above, and furthermore in view of **Falb** et al. (US 5242403; hereafter Falb), **Kramer** et al. (US 5938636; hereafter Kramer), or **Leslie** et al. (US 4,529,401; hereafter Leslie).

The Polaschegg, Winkler, and Altman patents do not disclose a temperature control system, a monitoring system, and a flow rate controller to monitor physiological

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conditions and moderate flow accordingly. However, these enhancements would have been considered well known in the art in view of the teachings of Falb, Kramer, and Leslie. The Falb patent demonstrates the conventionality of using a temperature control system within an infusion system to control the temperature of infusion fluids in a reservoir. Additionally, the Kramer patent discloses an infusion system having a monitoring and control system that monitor physiological conditions, and using a microprocessor, adjust flow characteristics accordingly. Finally, the Leslie patent demonstrates the conventionality of using flow rate control systems within an infusion system to accurately adjust and control fluid infusion.

Based on the teachings of Falb, Kramer, and Leslie, for a person of ordinary skill in the art, modifying the infusion system disclosed by Polaschegg with (1) a temperature control system, as taught by Falb, (2) an infusion system having a monitoring and control system that monitor physiological conditions, as taught by Kramer, and furthermore, (3) a flow rate control system, as taught by Leslie, would have been considered “**obvious to try**” since these enhancements were readily available technologies at the time the invention was made, and therefore, would have allowed the artisan to choose from a finite number of predictable solutions, as described by the teachings of the above cited patents, with a reasonable expectation of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM